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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/336,036	06/18/1999	PATRICK M. SCHLIEVERT	600.347USH	7188

23552 7590 12/05/2001

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/05/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/336,036

Applicant(s)

SCHLIEVERT ET AL.

Examiner

Ja-Na A Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request filed on September 17, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/336,036 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1, 3-10 and 17-19 are pending in this office action.

Withdrawal of Rejections

3. The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Goshorn et al., in view of Hartwig et al. is withdrawn in view of applicants arguments.

Response to Arguments

4. Applicant's arguments filed September 17, 2001 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 1, 3-10 and 17-19 under 35 U.S.C. 112, first paragraph, is maintained essentially for reasons set forth in the previous office action.

The rejection was on the grounds that the specification was enabled for a Streptococcal pyrogenic exotoxin type C (SPE-C) mutant with the specifically named amino acid substitutions in a Beta barrel of the B-subunit or a N-terminal alpha helix, but not reasonably enabled for a

Streptococcal pyrogenic exotoxin type C (SPE-C) mutant with more than one substitution for any amino acid in the Beta barrel of the B-subunit or a N-terminal alpha helix. Thus, the specification fails to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant urges that the specification is replete with information and guidance regarding which amino acids should be substituted and points to tables and examples. However, it is the examiner's position that amino acid substitution with out guidance leads to unpredictable mutants requiring undue experimentation. The specification teaches that it is preferred that the change in the amino acid sequence of the toxin does not result in a change if the toxin's ability to stimulate an antibody response that will neutralize wild type SPE-C toxin (page 9 lines 3-6); yet the claims do not encompass this limitation when claiming the at least one amino acid substitution. The specification discloses that it is preferred that amino acids in the N-terminal alpha helix have hydroxyl groups to interact with exposed amide nitrogens or that they be negatively charged to interact with the partial positive charge present at the N-terminus of the alpha helix; however the claims 1 and 19 do not incorporate this limitation (page 10 lines 20-24).


The specification, as discussed by applicant teaches specific positions and substituted amino acids. Yet the specification fails to teach that all the amino acids within the beta-barrel of the B-subunit or the N-terminal alpha helix can be substituted, which is what claims 1 and 19 encompass. There is no support in the specification for such a substitution. There is no teaching in the specification that all six position as recited in claim 19 will result in a mutant toxin disclosed by the claims. The specification fails to teach a mutant with substituted amino acids at positions 12, 15, 17, 35 and 38. The specification does not teach what these amino acids can be substituted with. The specification teaches specific positions for substitutions, the specification does not teach generic substitutions of any or all amino acids within the Beta barrel or N-terminal alpha helix.

Therefore, the specification is enabled for the specific amino acid substitutions and not for the breadth that the claims are drawn to. The prior art teaches that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect. Applicant has not taught without unpredictability and/or undue experimentation how to substitute the amino acids. Merely reciting substitution techniques does not provide guidance to one of skill in the art on what amino acids may or may not be substituted into the positions. The substitution of any amino acid in the recited location within the mutant SPE-C would not predictably result in a stable molecule. The specification only teaches the use of specific amino acids in specific locations which result in stable variations. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which substitutions would result in the toxin. Accordingly, one of skill in the art would be required to perform undue experimentation to use any amino acid at any location to produce a stable SPE-C toxin. Thus, the rejection is maintained.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 
November 27, 2001


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600